

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

----- x
In Re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

:
:
:
:
:
MDL No. 1456

----- x
THIS DOCUMENT RELATES TO:

:
:
:
:
:
Master File No. 01-CV-12257-PBS

State of Montana v. Abbott Laboratories, Inc.
et al., D Mont. Cause No. CV-02-09-H-DVM

:
:
:
:
:
Judge Patti B. Saris
----- x

**DEY, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO
DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT**

KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Attorneys for Dey, Inc.

Of Counsel:

Paul F. Doyle
Nell Merkl
Phillip D. Robben

I. INTRODUCTION

Pursuant to Rules 8(a), 9(b) and 12(b)(6) of the Federal Rules of Civil Procedure, all claims asserted by the State of Montana ("Montana") against Dey, Inc. ("Dey") in the Second Amended Complaint (the "Complaint") should be dismissed as to Dey with prejudice.¹

II. ALL CLAIMS AGAINST DEY SHOULD BE DISMISSED SINCE ALL DRUGS ATTRIBUTED TO DEY IN THE COMPLAINT ARE NON-INNOVATOR MULTIPLE SOURCE DRUGS

All of the drugs attributed to Dey in this action are non-innovator multiple source drugs, as that term is defined in the statute which provides for Medicaid rebates. *See* 42 U.S.C. § 1396r-8(k)(7)(A)(iii).² As such, for the reasons set forth in Point I of the Abbott Memorandum, all rebate claims asserted against Dey in this action should be dismissed since none of the conduct alleged by Montana would have had the effect of reducing Dey's rebate liability and, therefore, Montana's rebate claims as to the drugs attributed to Dey fail as a matter of law.

In addition, for the reasons set forth in Point II of the Abbott Memorandum, all other claims asserted against Dey should also be dismissed from this action since those allegations either: (a) concern the reimbursement of multiple source drugs as to which any alleged manipulation or overstatement of AWP could not have had any effect or (b) fail to satisfy Rules 8(a) and 9(b).

¹ Dey also joins in the Consolidated Memorandum of Law In Support of Defendants' Motion To Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint (the "Consolidated Memorandum"), which is incorporated herein by reference. Where indicated below, Dey also joins in the arguments asserted by Abbott Laboratories, Inc. ("Abbott") in Abbott's Separate Memorandum of Law In Support of Its Motion To Dismiss Montana's Second Amended Complaint (the "Abbott Memorandum").

² Montana impliedly concedes – as it must – that all drugs attributed to Dey in this action are non-innovator multiple source drugs. Indeed, the Complaint defines "generic" drugs as all drugs *other* than single source and innovator multiple-source drugs. (Complaint ¶¶ 127, 606.) Having so defined generic drugs, the Complaint then goes on to identify all of the drugs attributed to Dey which are at issue in this action via a chart which lists each of the drugs as "generic". (Complaint ¶ 386.)

III. MONTANA HAS FAILED TO SATISFY RULE 9(b)

Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." In the First Circuit, Rule 9(b) is "strictly applied". *New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 288 (1st Cir. 1987). Rule 9(b) requires that a plaintiff plead the "who, what, when, where, and how of the alleged fraud." See *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39, 46 (D. Mass. 2001) (Saris, J.). The Complaint wholly fails to meet this standard and should, therefore, be dismissed with prejudice. Several examples specific to Dey illustrate Montana's cavalier use of sweeping allegations of wrongdoing with no specificity to back them up.

A. Montana Pleads No Specifics As To Dey

Throughout the Complaint, Montana makes conclusory allegations charging defendants with fraud and various types of associated wrongdoing. For example, the Complaint contends that "defendants" – including Dey – "specifically instructed and expected providers to charge the inflated AWP's for drugs to Medicare, Medicaid, and Patients making co-payments." (Complaint ¶ 180.) Montana also alleges that the defendants provided a variety of benefits to providers to induce them to purchase products, including giving free samples, volume discounts, rebates, "off-invoice pricing", free goods, "credit memos", consulting fees, debt forgiveness, educational grants, and promotional grants. (Complaint ¶¶ 181, 184.) With regard to its allegations regarding free samples, Montana goes so far as to allege that all "defendants specifically told physicians to bill the Montana Medicaid Program and others for free samples, which defendants know was unlawful." (Complaint ¶ 181.) All of these allegations are made generally and without any attempt to provide specific instances of wrongful conduct by Dey.

Even those paragraphs of the Complaint which specifically concern Dey fail to meet plaintiffs' Rule 9(b) burden in that they fail to meet Montana's burden to provide Dey with the who, what, when, where and how of the alleged fraud. These paragraphs contain nothing more than

innuendo and the mere suggestion that Dey has committed fraud. For example, Montana dwells at length on the fact that Dey has been the subject of several on-going investigations and that Dey is a defendant in lawsuits brought by the attorney generals of West Virginia, Connecticut and, formerly, Texas. (Complaint ¶¶ 404-409.) Yet mere reference to those investigations or lawsuits does not satisfy plaintiffs' obligation to plead specifics as to Dey. *See Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996) ("[M]ere allegations of fraud, . . . or referrals to plans and schemes are too conclusional to satisfy the particularity requirement, no matter how many times such allegations are repeated.") (quoting *Hayduck v. Lanna*, 775 F.2d 441, 444 (1st Cir. 1985)).

In a single paragraph, plaintiffs do allege various correspondence between Dey and the publishers of industry pricing compendia concerning the subject of AWP and WAC figures for a few Dey products. (Complaint ¶ 388.) However, none of this correspondence demonstrates that the AWP figures at issue in that correspondence were, in fact, fraudulent. Likewise, the other out-of-context quotes from a few Dey documents and the various tables Montana sprinkles throughout its allegations concerning Dey similarly do nothing to demonstrate that Dey's AWP figures were "fraudulent", "manipulated" or otherwise part of a "scheme".³ Moreover, plaintiffs' conclusory allegations and out-of-context discussion of two Dey documents in paragraphs 393-397 of the Complaint cannot save the Complaint from dismissal under Rule 9(b). These allegations amount to nothing more than a claim that Dey was aware that reimbursement rates were a factor in its customers' purchasing decisions; none of these allegations particularize a scheme whereby Dey

³ Nor does Montana's reference in paragraph 392 of the Complaint to a single document from 1992 which talks about the spread in the context of competition demonstrate that Dey engaged in a scheme to commit fraud. Moreover, Montana fails allege, yet alone particularize, how the matters referred to in the document had any actual effect on the amounts paid for drugs by Montana or payors located in Montana. Moreover, the document is only one from nearly 200,000 pages of documents Dey produced in the class action case before the Court and is over 11 years old. Montana fails to show how such an isolated, aged document lends support to the notion that Dey engages in a "pattern of fraudulent conduct in artificially inflating the AWP's for drugs" (Complaint ¶ 174) (emphasis added).

committed fraud by "manipulating" AWP or otherwise. Finally, Montana's failure to particularize any of the prices it or third-parties paid for Dey's drugs is fatal to Montana's claims.⁴

B. Plaintiffs Resort To The Use Of Manufactured "Evidence"

In recognition of the utter lack of specificity in their allegations as to Dey, Montana attempts to demonstrate fraud by Dey by presenting evidence it simply manufactured. In paragraph 398 of the Complaint, Montana presents a table which it alleges is "excerpted" from a document Dey previously produced. The last column in Montana's table is titled "% Spread" – purporting to be evidence of Dey's marketing of a spread between its reported AWP and its customer's actual acquisition cost. (Complaint ¶ 398, Table 1.) In fact, the table is nothing more than a misleading fabrication Montana uses in an attempt to give its fraud claims a veneer of credibility. Annexed hereto as Exhibit A is a copy of the Dey document which Montana cites as the source for Table 1. As even a cursory review demonstrates, the "% Spread" column purportedly excerpted by Montana does not exist. Dey's attorneys have reviewed all documents of the type plaintiffs cite as the source for Table 1; none of those documents contain a "% Spread" or similar column either. Montana's resort to manufactured evidence to buttress their claims should be rejected.

C. Dey's Action Against First Data Bank Is Irrelevant To This Action

As did the class action plaintiffs in the AMCC, whose counsel also represents Montana here, Montana quotes at length from the complaint in a lawsuit Dey initiated against First DataBank and Medi-Span (the "FDB Action"). The FDB Action is irrelevant to the issues here. The FDB Action was initiated because First DataBank and Medi-Span began publishing Dey's AWP

⁴ In paragraphs 402-403 of the Complaint, Montana attempts to particularize its allegations as to Dey concerning improper incentives. Even taken at face value for purposes of this motion, all Montana can point to regarding "free goods" is one sentence from a document taken out of context which does not indicate that Dey was providing improper incentives. Montana's allegations of improper incentives are completely conclusory and provide absolutely no details as to the allegedly improper conduct. Certainly nothing Montana alleges in these two paragraphs comes close to showing that Dey "specifically told physicians to bill the Montana Medicaid Program" for anything, as alleged in paragraph 181 of the Complaint.

numbers using a method and procedure completely different from that used for reporting AWP's of Dey's competitors. The most that the FDB Action stands for is that, in certain contexts, published pricing information forms the basis for the amount paid to providers for drugs. Nothing in the FDB Action supports the assertion that Dey (or any other defendant) engages in AWP manipulation or any other fraudulent scheme involving AWP data.

IV. CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum and the individual memoranda of other defendants addressing common issues, the Court should dismiss the Second Amended Complaint as to Dey with prejudice.

Dated: September 15, 2003

Respectfully submitted,

KELLEY DRYE & WARREN LLP

By: 

Paul F. Doyle

Neil Merkl

Philip D. Robben

101 Park Avenue
New York, New York 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Attorneys for Dey, Inc.

Exhibit A

**Dey, Inc.'s Memorandum of Law In Support
of Its Motion To Dismiss The State of
Montana's Second Amended Complaint**

DEY LABORATORIES
2571 Napa Valley Corporate Drive
Napa, CA 94556
1-800-755-5580

12/20/95

McKESSEN DRUG COMPANY
Source Program Proposal

McK Econo	Generic Name	Strength	Size	No. Ctn.	Product #	Brand Name	AWP	WAC	Suggested Self Price	Source Net Price	% Discount from WAC
3286028	Acetylcysteine Solution	10%	4 mL	12	18104	Mucomyst	67.80	25.80	18.00	15.48	-40.0%
3284007	Acetylcysteine Solution	10%	10 mL	3	18110	Mucomyst	40.26	15.27	13.50	10.69	-30.0%
3225285	Acetylcysteine Solution	10%	30 mL	3	18130	Mucomyst	110.48	41.97	33.50	27.28	-35.0%
3286044	Acetylcysteine Solution	20%	4 mL	12	18204	Mucomyst	81.38	31.08	21.50	18.65	-40.0%
2474112	Acetylcysteine Solution	20%	10 mL	3	18210	Mucomyst	48.66	18.57	16.20	12.88	-30.0%
3286143	Acetylcysteine Solution	20%	30 mL	3	18230	Mucomyst	133.43	50.84	39.80	32.92	-35.0%
3225323	Acetylcysteine Solution	20%	100 mL	1	18200	Mucomyst	92.21	75.90	59.90	45.54	-40.0%
1615160	Abrudrol Sulfate Inhalation Soln.	0.083%	3 mL	25	69703	Proventil	30.25	14.50	12.00	10.25	-29.3%
1160233	Abrudrol Sulfate Inhalation Soln.	0.083%	3 mL	30	69733	or	36.30	17.40	14.40	12.30	-29.3%
2442119	Abrudrol Sulfate Inhalation Soln.	0.083%	3 mL	60	69760	Ventolin	72.60	34.50	28.80	24.60	-26.7%
1162509	Cromolyn Sodium Inhalation, USP	20 mg/2 mL	2 mL	60	69802	Intal	42.00	34.20	29.00	25.65	-25.0%
1161803	Cromolyn Sodium Inhalation, USP	20 mg/2 mL	2 mL	120	69812	Intal	84.00	68.00	58.00	51.30	-22.0%
3427804	Metaproterenol Sulfate Inhalation Soln.	0.4%	2.5 mL	25	67803	Akupent	30.75	11.00	10.00	8.84	-21.5%
3614757	Metaproterenol Sulfate Inhalation Soln.	0.6%	2.5 mL	25	67803	Akupent	30.75	11.00	10.00	8.64	-21.5%
1108871	Sodium Chloride Solution	0.9%	3 mL	100	83003	--	24.20	13.00	10.94	8.75	-32.7%
1107853	Sodium Chloride Solution	0.9%	5 mL	100	83005	--	24.20	13.00	10.94	8.75	-32.7%

Ord. # A16 M01

325896A

? 14.00 1250

all start date
p/p to mgs
per mgs waiting for
DL-PX 90011179